IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
NORTHEASTERN DIVISION

The University of Manitoba, a Manitoban Body Corporate, Plaintiff, vs. Drägerwerk AG & Co. KGaA, a German Limited Partnership, and Draeger Medical, Inc., a Pennsylvania Corporation, Defendants.	)	Civil Case No. 2:13-cv-48

Final Claim Construction of "Controlled Life Support Conditions" in Claims 1, 2, and 3 of U.S. Patent No. 5,647,350 (the '350 Patent")

This matter is before the Court on the issue of patent claim construction pursuant to Markman v. Westview Instruments, Inc.,[1]. The subject invention generally pertains to varying the flow of biological fluids to an organ during "controlled life support conditions." Plaintiff initially sued Drägerwerk AG & Co. KGaA, a German Limited Partnership, and Draeger Medical, Inc., a Pennsylvania Corporation. The Court dismissed Drägerwerk AG & Co. KgaA for lack of personal jurisdiction.[2]

On February 18, 2014, Plaintiff the University of Manitoba filed its claim construction brief.[3] Defendant Draeger Medical, Inc. filed its responsive claim construction brief on March 4,

[1] 517 U.S. 370 (1996).

[2] Doc. #80.

[3] Doc. #69.

2014,[4] and an amended responsive brief on March 6, 2014.[5] The University of Manitoba filed a reply brief on March 11, 2014.[6] A Markman[7] hearing was held on April 17, 2014 on the disputed claim term "controlled life support conditions".

The Court inquired of the parties whether they had an interest in receiving the Court's tentative draft rulings on claim construction before the scheduled Markman hearing. Courts have found this procedure useful for focusing the parties' arguments on true disputes about the construction of pertinent claims as well as on specific parts of the court's tentative claim constructions where they believe the court had gone wrong. Both sides in this case recommended this Court follow such a procedure. The Court provided the parties with a tentative draft ruling on claim construction prior to the Markman hearing.

At the Markman hearing, Draeger sought to present three new pieces of evidence: (1) an article entitled Combined Unilateral High Frequency Jet Ventilation and Contralateral Intermittent Positive Pressure Ventilation authored by B.A. Morgan, D. Perks, I.D. Conacher, and M.L. Paes; (2) United States Patent No. 6,269,813 B1 (Fitzgerald); and (3) United States Patent Application 2011/0180063 A1 (Hunsicker)[8]. The University of Manitoba objected to introduction of the new evidence. The Court found that the evidence was not timely disclosed, and Draeger failed to provide an adequate explanation for the late disclosure. The Court

[4] Doc. #74.

[5] Doc. #75.

[6] Doc. #76.

[7] 517 U.S. 370 (1996).

[8] Doc. #90.

indicated at the hearing that it either would decline to consider the new evidence, or it would allow the University of Manitoba an opportunity to present a written response to the new evidence. The University of Manitoba elected not to respond to the new evidence. The Court finds that the newly presented evidence does not enlighten the claim construction issues, and it has not relied on the evidence to construe the claims. The record now being complete, the Court issues this final claim construction order.

At the Markman hearing the University of Manitoba reiterated that the term "primary" must be given its plain and ordinary meaning, and the Court's tentative claim construction improperly ignores that meaning. The University of Manitoba also asserted that the Court erred in its tentative analysis when it relied on "sound bites" in the prosecution history and failed to consider the entire history. In doing so, the University of Manitoba contends that the Court incorrectly used the prosecution history to vary the plain language of the claims. The Court, after reexamining the claims and the prosecution history, restudying the prior art, and carefully considering the University of Manitoba's arguments, finds that the Court's tentative analysis continues to be correct.

BACKGROUND

In applying the Phillips[9] methodology, the Court's recitation of the factual background focuses on the patent-in-suit, including the words of the patent claims at issue in this infringement suit. The prosecution history is not recounted here. Any pertinent parts of the prosecution history is reserved and will be recounted when, and if, resort to the prosecution history for guidance is appropriate.

[9] Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005).

1. The Parties

The University of Manitoba (hereafter "the U of M") is located in Winnipeg, Manitoba, Canada. The U of M is the assignee of U.S. Patent No. 5,647,350 (the '350 Patent), the patent-in-suit.

Draeger Medical, Inc. (hereafter "Draeger") is a Pennsylvania Corporation with a principle place of business in Telford, Pennsylvania.[10] The U of M alleges Draeger sells a "Variable Pressure Support" ("VSP") option on some of its medical ventilators in the United States. Draeger asserts that the VSP option on its ventilators only functions when there is "patient breathing efforts." Thus, according to Draeger, once a patient's breathing effort is detected, the VSP provides partial assistance to support the patient's own breathing. If the patient ceases breathing efforts, Draeger's ventilator alarms out of the VSP mode and begins a different mode of controlled patient ventilation. The U of M alleges that Draeger's ventilator containing the VSP option infringes on its patent.

2. The Patent-in-Suit

a. The Inventors and Dates of Filing and Issuance

As noted earlier, the U of M is the assignee of the '350 Patent. The inventors are identified as William Alan C. Mutch and Gerald Robin Lefevre.[11] The '350 Patent stems from Application No. 404,464, filed on March 15, 1995.[12] The patent issued on July 15, 1997.[13]

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[10] Doc. #84, p. 3 ¶ 8.

[11] Doc. #1-1, p. 1.

[12] Doc. #1-1, p.1.

[13] Doc. #1-1, p. 1.

b. The Abstract and Field of the Invention

The Abstract of the '350 Patent briefly summarizes the invention as computer controlling the flow of biological fluid to an organ so that the natural variation of the flow is simulated.[14] The Abstract specifically describes control of a blood pump flow output during cardiopulmonary bypass to mimic normal pulsatile blood flow from the heart and control of a ventilator output to mimic normal breathing of healthy lungs.[15]

The Field of Invention, which follows, is only slightly more illuminating:

> The present invention relates to medical life support systems, and, in particular, to the control of cardiopulmonary bypass pumps for open heart surgery and mechanical ventilators to lungs.[16]

c. Background to the Invention

The Background to the Invention provides some further context to the subject invention. It explains that during cardiopulmonary bypass surgery, the heart is stopped and the blood which normally returns to the right side of the heart passes through a pump and oxygenating system and is returned to the aorta, thereby bypassing the heart and lungs.[17] During the procedure, the flow of blood is "essentially non-pulsatile with a low amplitude waveform having monotonous regularity."[18] Consequences identified with conventional non-pulsatile cardiopulmonary bypass include metabolic acidosis, interstitial fluid accumulation, elevated system vascular resistance,

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[14] Doc. #1-1, p. 1.

[15] Id.

[16] Doc. #1-1, p. 41, column 1.

[17] Doc. #1-1, p. 41, column 1.

[18] Id.

arteriovenous shunting and impair brain oxygenation.[19] According to the Background, because the monotonous regularity of pumping blood during cardiopulmonary bypass and a set tidal volume and respiratory rate of a mechanical ventilator is "in contrast to the intrinsic spontaneously variable rhythms of heart rate, blood pressure, and respiration" associated with a normal functioning heart and lungs, the invention sought to improve the safety and reduce the consequences of open heart surgery.[20]

d. Summary of the Invention

The Summary of the Invention reiterates the purpose of the invention is to regulate the control of flow of biological fluid to an organ in a manner "that closely mimics" natural variation.[21] The manner of controlling the biological fluid to the organ depends on the fluid and the organ concerned.[22] The Summary of the Invention sets forth a number of steps pertaining to the invention: First, a pattern of instantaneous changes in the flow of a biological fluid to an organ is generated.[23] Next, a variable control parameter is generated for regulation of flow of the biological fluid to the organ in accordance with the pattern.[24] The last step is to control the flow of the biological fluid to the organ according to the variable control parameter.[25]

The Summary of the Invention notes that the subject invention "is applicable not only to

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[19] Id.

[20] Id.

[21] Doc. #1-1, p. 41, column 2, lines 2-7.

[22] Doc. #1-1, p. 41, column 2, lines 64-66.

[23] Doc. #1-1, p. 41, column 2, lines13-15.

[24] Doc. #1-1, p. 41, column 2, lines 32-34.

[25] Doc. #1-1, p. 41, column 2, lines 58-60.

control of a cardiopulmonary bypass pump or a mechanical ventilator but also to any other operation or device involving this control of a biological fluid to any organ." [26] It includes, as examples, utilizing the principles for intra aortic balloon counterpulsation, improving hemodialysis, applying the principles during extracorporeal membrane oxygenation, using in conjunction with right and left ventricular assist devices, and using in the perfusion of organs prior to transplantation.

e. Drawings

The drawings describing the invention include flow diagrams, graphs, profiles, line charts, line chart comparisons, and block diagrams.[27] They assist in explaining, for example, the steps of operation for a cardiopulmonary pump, the typical plot of natural variation of systolic blood pressure and respiratory rate, and a typical pump pulsation profile controlled in accordance with the invention compared with a plot of natural variations in blood pressure.[28] The drawings do not provide guidance for the disputed term.

f. Summary of Disclosure

The Summary of Disclosure, while a concise synopsis, does not shed additional light on the subject invention. It provides:

> the present invention provides computer control of the operation of a cardiopulmonary bypass pump, a lung ventilator or other device which provides simulation of in vivo variability of flow of a biologic fluid to an organ.[29]

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[26] Doc. #1-1, p. 42, column 3.

[27] Doc. #1-1, pp. 2-40; pp. 42-43, columns 3 - 5.

[28] Id.

[29] Doc. #1-1, p. 47, column 14.

The Summary of Disclosure does not limit the subject invention to cardiopulmonary bypass pumps or ventilators, noting "[m]odifications are possible within the scope of this invention.[30]

g. Claims

The '350 Patent contains the following specific claims:

1. A method of controlling flow of a biological fluid to an organ during controlled life support conditions, said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method which comprises:

establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal organ of a mammalian species,

generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and

controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.

2. A method of controlling flow of ventilating gas from a ventilator device to the lungs of a body during controlled life support conditions, said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method comprises:

established a predetermined pattern of variation over time of instantaneous respiratory rate and tidal volume of the independently-functioning normal lungs of a mammalian species,

generating a signal corresponding in value to an individually-determined respiratory rate and tidal volume in said predetermined pattern,

generating a control voltage corresponding in magnitude to said signal,

applying said control voltage to said ventilator device to provide an output of ventilating gas from said ventilating device of a respiratory rate proportional to the magnitude of said signal, and

repeating said steps of generating a signal, generating a control voltage and applying said control voltage to said ventilator device for each next individually-determined respiratory rate of said predetermined pattern, to provide a variable flow of ventilating gas from the ventilator device to the lungs of the body under controlled life support conditions which mimics

[30] Id.

normal breathing of healthy lungs.

3. Apparatus for controlling the flow of biological fluid to an organ, said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method comprises:

means for establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal organ of a mammalian species,

means for generating a variable control parameter for regulation of flow of the biological fluid to an organ during controlled life support conditions in accordance with the predetermined pattern, and

means for controlling the flow of the biological fluid to the organ during controlled life support conditions in accordance with the variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.[31]

h. Disputed Constructions

The parties propose divergent claim constructions for the term "controlled life support conditions." The U of M contends that "controlled life support conditions" includes conditions in which a medical life support system is the primary, not necessarily sole, source of biological fluid to an organ. Draeger counters that "controlled life support conditions" as used in the subject invention must be interpreted to mean there is no patient breathing effort. Draeger urges that the term "primary source" pertains to the biological fluid and it has no "logical or technical connection" to "controlled life support conditions."[32]

DISCUSSION

1. Claim Construction Principles

Patent claim construction – the interpretation of the patent claims that define the scope of

[31] Doc. #1-1, columns 249 & 250.

[32] Doc. #75, p. 18.

the patent – is a matter of law for the court.[33] "[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude."[34] Claim construction requires an examination of the intrinsic evidence of record, including the claims of the patent language, the specification, and the prosecution history.[35] The starting point for claim construction is a review of the words of the claims themselves. The terms used in the patent are presumed to carry "the meaning that the term would have to a person of ordinary skill in the art at the time of the invention.[36] Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, a court may look to the sources available to the public that show what a person of skill in the art would have understood the claim language to mean.[37]A court may use a dictionary to "assist in understanding the commonly understood meaning" of a term, so long as any meaning found in such sources does not contradict the definition that is found in the patent documents.[38] In other words, a court must ensure that any reliance on dictionaries accords with the intrinsic evidence: the claims themselves, the specification, and the prosecution history.[39]

Second, a court considers the entire specification to define technical terms that might not

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[33] Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996).

[34] Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111,1115 (Fed. Cir. 2004)).

[35] Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

[36] Phillips, 415 F.3d at 1313.

[37] Id. at 1314.

[38] Id. at 1322-23.

[39] Id. at 1314.

lend themselves to an ordinary meaning. The specification is "the single best guide to the meaning of a disputed term." [40] The specification may prescribe a special definition given to a claim term, or a disavowal of a claim scope by the inventor.[41] In such cases, the inventor's intention that is expressed in the specification is dispositive.[42] A court may not, however, import limitations from the specification into the claims.[43] To avoid importing limitations from the specification into the claims, a court considers that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so.[44]

Third, intrinsic evidence also includes the patent's prosecution history, which contains evidence of the United States Patent and Trademark Office (hereafter "PTO") and the inventor's understanding of the patent.[45] The prosecution history includes the record of the proceedings before the PTO and any prior art cited by the applicant.[46] Because the prosecution history lacks the clarity of the specification, it is less useful.[47] Nevertheless, an explicit statement made by an applicant during the patent's prosecution may serve to narrow the scope of the claim.[48] "The

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[40] Id. at 1315.

[41] Id. at 1316.

[42] Id.

[43] Id. at 1323.

[44] Id.

[45] Id. at 1317.

[46] Id.

[47] Id.

[48] Spectrum Int'l v. Sterilite Corp., 164 F.3d 1372, 1378-79 (Fed. Cir. 1988).

purpose of consulting the prosecution history in construing a claim is to 'exclude any interpretation that was disclaimed during prosecution.'" [49]

If after an examination of the intrinsic evidence the court finds the claim ambiguous, the court may look to extrinsic evidence, including expert and inventor opinions, treatises, and articles.[50] Courts are to look to extrinsic evidence as a last resort, as it is less reliable than intrinsic evidence.[51] In addition, extrinsic evidence must be considered in the context of intrinsic evidence.[52]

2. Other Canons of Claim Construction

Apart from the evidence upon which claim construction may be based, claim construction involves various "canons." One canon of claim construction is that "claim terms are presumed to be used consistently throughout the patent, such that the usage of a term in one claim can often illuminate the meaning of the same term in other claims." [53] It follows then that "[w]hen different words or phrases are used in separate claims, a difference in meaning is presumed."[54] Likewise, a court must interpret claims so that no term becomes "superfluous." [55]

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[49] Research Plastics, Inc. v. Federal Packaging Corp., 421 F.3d 1290, 1296 (Fed. Cir. 2005) (quoting Rhodia Chimie v. PPG Indus., 402 F.3d 1371, 1384 (Fed. Cir. 2005)).

[50] Phillips, 415 F.3d at 1317.

[51] Id. at 1317-18.

[52] Id. at 1318-19; Network Commerce, Inc. v. Microsoft Corp., 422 F.3d 1353, 1361 (Fed. Cir. 2005).

[53] Research Plastics, Inc., 421 F.3d at 1295.

[54] Nystrom v. TREX Co., Inc., 424 F.3d 1136, 1143 (Fed. Cir. 2005) (citing Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.3d 1017, 1023 (Fed. Cir. 1987)).

[55] See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 2372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.").

Another canon of claim construction is that the patentee may act as "lexicographer." In other words, "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess," and when that happens, the patentee's definition must govern.[56] The authority of the specification as a source for definitions for claim terms, however, is not limitless. A court must take care not to import a limitation from the written description; instead, it must use the written description for enlightenment.[57]

3. The Court's Independent Obligation to Construe Terms

The Federal Circuit Court of Appeals has expressly held that a court is free to adopt a construction independent of those suggested by the parties.[58] Accordingly, the Court has an obligation to construe the patent terms independently, apply the Phillips methodology, and is not bound to adopt either party's proffered construction of any claim terms.

With these principles in mind, the Court turns to construction of the disputed claim terms of the '350 Patent.

4. The '350 Patent

The Court first looks to the words of the claims, giving them the plain meaning for a person of ordinary skill in the art in question at the time of the invention. Three claims are contained in the '350 Patent. Each claim contains the disputed term "controlled life support conditions". Draeger contends that "controlled life support conditions" is limited to situations where there is no patient breathing effort. The U of M counters that Draeger's construction

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[56] Phillips, 415 F.3d at 1316.

[57] Playtex Prods, Inc. v. Proctor & Gamble Co., 400 F.3d 901, 906 (Fed. Cir. 2005) (citing Comark Communications v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed. Cir. 1998)).

[58] Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1555 (Fed. Cir. 1995).

improperly limits the scope of the invention such that the patent-in-suit applies where biological fluid is the primary source of fluid, and not necessarily the sole source, to sustain life support to an organ.

a. Claim Terms and Specification

In the first amendment, the patentee added the term "controlled life support conditions." This term is not defined, described, or found anywhere else in the specification of the patent. There is no evidence in the record from which this Court can conclude the term has an ordinary meaning to those skilled in the field. The claim language, itself, does not resolve the parties' dispute. It is, however, arguable whether controlled life support conditions is limited to those situations where there is no patient breathing effort.

The plain language of the claims suggest that the biological fluid must be the primary source of fluid to sustain life to the organ. Looking to the specification, the U of M correctly points out that the background section references healthy patients being ventilated during elective surgery.[59] Such a scenario may very well encompass situations where there is some patient breathing effort. Likewise, the background also notes that prevention of alterations in respiratory function would represent "a major advance in management of all patients requiring ventilatory support."[60] Thus, at first blush, the scope of the invention appears to encompass a variety of patient conditions, ranging from situations where there is some patient breathing effort to no patient breathing effort. Nonetheless, the U of M's proposed construction falls apart after the prosecution history is considered.

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[59] Doc. #1-2, p. 41, column 1, lines 48-49.

[60] Id. at p. 41, column 1, lines 51-53.

b. Detailed Prosecution History

When a patentee unequivocally disavows a certain meaning to the patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim.[61] The patent-in-suit, Application Number 404,464 filed on March 15, 1995, identified four claims. Claim 2 was withdrawn from consideration.[62] Upon review by the PTO, the Examiner rejected Claims 1, 3, and 4 on the basis that they were unpatentable because of a prior art patent - U.S. 4,448,192 (Stawitcke).[63] Post-Markman hearing, the Court has restudied the Stawitcke patent in light of the U of M's arguments. Stawitcke involves a ventilator that accommodates a patient's breathing efforts through the use of a "novel control law."[64] The identified novel pressure-volume control law determines a target ideal pressure-volume wave-form, which is then modified during the ventilator operation to enable the patient to breathe with minimum ventilation opposition or fighting.[65] Stawitcke improved the prior art by regulating pressure as a function of volume during inhalation and exhalation instead of controlling the pressure or flow as a function of time.[66] In other words, Stawitcke describes a ventilator adapting to patient activity to ensure the target ventilation is reached through the delivery of a target volume.

During prosecution of the patent-in-suit, the patentee differentiated the prior art:

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[61] Shire Development, LLC v. Watson Pharmaceuticals, Inc., - - F.3d - -, 2014 WL 1258136, *4 (Fed. Cir. 2014) (quoting Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003)).

[62] Doc. #74-5 (First Office Action).

[63] Id.

[64] Doc. #74-3, p. 2 of 20, Abstract.

[65] Id.

[66] Id. at p. 13 of 20, column 4, lines 5-11.

The Stawitcke devices as relied on by the Examiner is concerned primarily with the weaning type of ventilator which provides assisted ventilation to a patient rather than the present invention which is concerned with ventilation during controlled life support conditions. . . . Th[e] [Stawitcke] system provides for a variable degree of assistance, depending on the degree of patient effort and provides the assisted ventilation in accordance with the described pressure-volume law, the parameter of which can be changed in response to measurements and calculations relating to parameters, such as compliance and resistance.[67]

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. . .What is described in Stawitcke in Col. 5 is how the system accommodates patient effort while still maintaining the required target volume and the point at which the positive pressure control law takes over. . . . The passage in Col. 7 to which the Examiner refers simply indicates that the target pressure is preset by the clinician and the pressure-volume wave form required for the particular patient is constantly computed and applied. In the present invention, there is no patient effort to be taken into consideration and the variation in respiratory rate and tidal volume is predetermined from a pattern taken from a healthy mammal.[68]

It is clear, therefore, that the Stawitcke reference is concerned with quite different circumstances from the present invention. As already noted, the Stawitcke reference is concerned primarily with the weaning type of ventilator wherein gas flow to the patient is controlled in accordance with a pressure-volume control law to ensure the delivery of a target volume to the weaning patient while taking into account patient effort. In the absence of patient effort, the system described by Stawitcke will deliver a monotonously regular tidal volume and respiratory rate according to the preset values programmed by the operator.[69]

In contrast, in the present invention, the ventilator is operating during controlled life support conditions where there is no patient effort to be taken into consideration. Rather than provide a monotonous flow of gas to the patient, a variable flow is provided in accordance with a predetermined pattern of instantaneous respiratory rate and tidal volume which is established from the healthy lungs of a mammal . . .[70]

The patentee made plain in its first amendment that Stawitcke involved a ventilator

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[67] Doc. #74-6, p. 5 of 8 (First Amendment).

[68] Id. at p. 7 of 8.

[69] Id.

[70] Id. at pp. 7-8 of 8.

operating under weaning conditions where there is some patient breathing effort and the subject invention pertained to a ventilator operating during controlled life support conditions where there is no patient breathing effort to be taken into consideration. Accordingly, Claim 1 of the subject invention, which was initially identified, in part, as "[a] method of controlling flow of a biological fluid to an organ", was amended to read, in part, "[a] method of controlling flow of a biological fluid to an organ during controlled life support conditions . . ." [71] Similarly, Claim 3 initially identified, in part, as "[a] method of controlling flow of ventilating gas from a ventilator device to the lungs of a body" was amended to read, in part, "[a] method of controlling flow of ventilating gas from a ventilator device to the lungs of a body during controlled life support conditions . . .".[72]

On March 18, 1996, the PTO, again, rejected all claims. This time the Examiner found the claims in the subject invention were unpatentable over U.S. 4,584,996 (Blum).[73] The Examiner explained that Blum discloses a method for gathering "normal" breathing data to be applied subsequently to match "normal" demand, and although there is no mention of "controlled life support conditions", the method applies to a variety of patient care settings, which "would have been obvious to one having ordinary skill in the art."[74]

The patentee submitted amendments to the claims. This time the method set forth in Claim 1 read as follows: controlling biological fluid to an organ during controlled life support

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[71] Id. at p. 2 of 8 (emphasis in original).

[72] Id.

[73] Doc. #74-7 (Second Office Action).

[74] Id. at pp. 2-3 of 8.

conditions in accordance with the variable control parameter "to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ." [75] The patentee re-explained that the purpose of the invention was "to provide a pattern of flow of the biological fluid to the organ which mimics normal flow to a healthy organ." [76] The patentee described the invention under consideration as "a mechanical ventilator which in a controlled life support scenario, wholly controls the flow of ventilating gas to the lungs of the patient under life support."[77]

Additionally, the patentee distinguished the environment in which Blum's procedure may be employed.[78] The patentee asserted that Blum applies to the specific condition of providing oxygen therapy for a C.O.L.D. [chronic obstructive lung disease] patient by providing supplemental oxygen while not otherwise altering the pressure relationships within the respiratory tract or the volume of the gas inhaled.[79] In other words, there is no determination in Blum made with respect to a "normal independently functioning organ."[80] Instead, according to the patentee, the Blum patent provides for a single determination of respiratory rate and that rate is used in combination with the oxygen level determination; therefore, the only "pattern" that exists is a continuous flow of supplemental oxygen during the inspiratory phase during

[75] Doc. #74-8 (Second Amendment).

[76] Id. at p. 5 of 11.

[77] Id.

[78] Id. at p. 5 of 11.

[79] Id. at p. 6 of 11.

[80] Id. at p. 7 of 11.

predetermined on-cycles and ceasing that flow during a predetermined number of off-cycles.[81]

The Examiner interviewed the applicant on September 20, 1996.[82] The Examiner noted that there was an agreement to amend the claims "to have the biological fluid as the primary source of fluid to sustain life."[83] He also noted the distinction regarding prior art: "Blum teaches oxygen biological fluid as a secondary source."[84] He further concluded that the claims would be allowed with the amendment.[85] A Notice of Allowability was issued on February 3, 1997.[86] The Examiner's amendment provided that Claim 2 had been cancelled and Claims 1, 3, and 4 contained the following additional language: "said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method - -."[87]

c. Brief Summary of Claim Progression

For purposes of the construction of the disputed term, Claim 1 is exemplary of the three claims contained in the '350 Patent. The following summary compares the changes with regard to Claim 1 as initially proposed and as ultimately allowed:

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[81] Id.

[82] Doc. #74-9 (Examiner Interview Summary Record).

[83] Id.

[84] Id.

[85] Id.

[86] Doc. #74-10 p. 2 of 6.

[87] Id. at p. 3 of 6.

As Filed on 3/15/1995	**1st Office Action Response 2/15/1996**	**2nd Office Action Response 7/2/1996**	**Claims as Allowed on 2/3/1997**
A method of controlling flow of a biological fluid to an organ, which comprises:	A method of controlling flow of a biological fluid to an organ during controlled life support conditions, which comprises:	A method of controlling flow of a biological fluid to an organ during controlled life support conditions, which comprises:	A method of controlling flow of a biological fluid to an organ during controlled life support conditions, said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method which comprises:
establishing a pattern of variations over time of instantaneous changes in flow of a biological fluid to an organ of a mammalian species,	establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to independently-functioning normal [an] organ of a mammalian species,	establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal organ of a mammalian species,	establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal organ of a mammalian species,
generating a variable control parameter for regulation of flow of said biological fluid to an organ in accordance with said pattern, and	generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and	generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and	generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and
controlling said flow of said biological fluid to said organ in accordance with said variable control parameter.	controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter.	controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.	controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.

The focus of the parties' dispute is on whether the term "primary source" of the biological fluid modifies controlled life support conditions or simply differentiates the subject invention from other inventions providing secondary or supplemental biological fluid, i.e. oxygen. The Court tentatively determined that the prosecution history demonstrates that the term "controlled life support conditions" focuses on the patient's condition. In light of the U of M's arguments at the Markman hearing to the contrary, the Court has re-examined the Stawitcke patent and the entire prosecution history. Upon re-examination, the Court finds the U of M's arguments unpersuasive.

In distinguishing the subject invention from Stawitcke, the patentee described the subject invention as one operating where there is "no patient effort to be taken into consideration." The patentee noted this distinction two separate times in the first amendment. The patentee also explained more than once that the subject invention was not similar to a weaning-type of ventilator that considers patient effort such as Stawitcke. These repeated statements made by the patentee constitute an unambiguous disavowal of the scope of the subject invention. The term "controlled life support conditions" as used in the subject invention pertains to situations where there is no patient breathing effort taken into consideration.

The U of M's arguments, which broaden the meaning of controlled life support conditions, focus on a second distinction made in response to the Examiner's rejection of the application over prior art. In a later amendment, the patentee explained that the biological fluid being provided to the patient in the subject invention was the primary rather than secondary or supplemental source of biological fluid (Blum). The term "primary source of fluid" was added at the end of the prosecution by the patentee in order to distinguish the subject invention from, for

example, a nasal cannula providing supplemental oxygen (Blum). In Blum, the flow rate of oxygen is constant. Variation in the system is tied to the number of on and off cycles to reach a specific predetermined level. There is no system in Blum that attempts to mimic the normal flow of biological fluid during controlled life support conditions. In light of the distinction being made by the patentee in response to the Examiner's reliance on Blum, there is no indication that the patentee's addition of the term "primary source of fluid" had anything to do with the meaning of "controlled life support conditions" previously claimed by the patentee to the Examiner. The U of M asks this Court to infer that the term "primary source" broadens the parameters of "controlled life support conditions" after the patentee had expressly claimed otherwise. It does not follow that the latter statements made to distinguish Blum control and the preceding statements made to distinguish Stawitcke are to be ignored. The U of M's proposed construction attempts to recapture through claim interpretation specific meanings disclaimed during prosecution.

A review of the intrinsic evidence as a whole reveals that the patent-in-suit applies during "controlled life support conditions" where no patient breathing effort is taken into consideration and the biological fluid needed to sustain life is the primary source of fluid, as opposed to a secondary or supplemental source. The U of M specifically disclaimed that its patent covers medical situations in which there is a patient under controlled life support conditions and the patient's breathing effort is to be taken into consideration.

d. Extrinsic Evidence

While courts may consider extrinsic evidence to educate themselves about the patent and technology at issue, it is improper to rely on extrinsic evidence in construing claims unless, after

consideration of all the intrinsic evidence, ambiguity remains.[88] Finding no ambiguity in the intrinsic evidence, the Court will not consider any extrinsic evidence.

CONCLUSION

The claim term in dispute, the parties' proffered construction, and the Court's own construction are summarized as follows:

Claim Term	**U of M's Construction**	**Draeger's Construction**	**Court's Construction**
controlled life support conditions	any patient condition so long as the biological fluid is the primary source to sustain life support to an organ	only patient conditions where there is no breathing effort	only patient conditions where there is no patient effort to be taken into consideration

The Court hereby adopts the foregoing as its final construction of the patent claim terms in dispute.

IT IS SO ORDERED.

Dated this 16th day of June, 2014.

/s/ Ralph R. Erickson
Ralph R. Erickson, Chief Judge
United States District Court

[88] Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc., 152 F.3d 1368, 1373 (Fed. Cir. 1998).